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| U.S. DEPARTMENT OF COMMERCE PATENT AND TRADEMARK OFFICE   |   | ATTORNEY'S DOCKET NUMBER<br><b>TANIKAWA1</b>                        |
| <b>TRANSMITTAL LETTER TO THE UNITED STATES<br/>DESIGNATED/ELECTED OFFICE (DO/EO/US)<br/>CONCERNING A FILING UNDER 35 U.S.C. 371</b>   |   | U.S. APPLICATION NO. (If known, see 37 CFR 1.5)<br><b>10/524019</b> |
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| INTERNATIONAL APPLICATION NO.<br><b>PCT/JP2003/010754</b>   | INTERNATIONAL FILING DATE<br><b>August 26, 2003</b> | PRIORITY CLAIMED<br><b>August 27, 2002</b>                          |
| TITLE OF INVENTION<br><b>METHOD FOR STABILIZING PROTEIN SOLUTION FORMULATIONS</b>   |   |   |
| APPLICANT(S) FOR DO/EO/US<br><b>Masahiko TANIKAWA et al.</b>  |   |   |
| <p>Applicant herewith submits to the United States Designated/Elected Office (DO/EO/US) the following items and other information:</p> <ol style="list-style-type: none"> <li>1. <input checked="" type="checkbox"/> This is a <b>FIRST</b> submission of items concerning a filing under 35 U.S.C. 371.</li> <li>2. <input type="checkbox"/> This is a <b>SECOND</b> or <b>SUBSEQUENT</b> submission of items concerning a filing under 35 U.S.C. 371.</li> <li>3. <input checked="" type="checkbox"/> This is an express request to begin national examination procedures (35 U.S.C. 371(f)) as soon as the application is in order for such purpose and the applicable requirements of 35 U.S.C. 371(c) have been complied with.</li> <li>4. <input checked="" type="checkbox"/> The US has been elected (Art 31).</li> <li>5. <input checked="" type="checkbox"/> A copy of the International Application as filed (35 U.S.C. 371(c)(2))             <ol style="list-style-type: none"> <li>a. <input type="checkbox"/> is attached hereto (required only if not transmitted by the International Bureau).</li> <li>b. <input checked="" type="checkbox"/> has been communicated by the International Bureau.</li> <li>c. <input type="checkbox"/> is not required, as the application was filed in the United States Receiving Office (RO/US).</li> </ol> </li> <li>6. <input checked="" type="checkbox"/> An English language translation of the International Application as filed (35 U.S.C. 371(c)(2)).             <ol style="list-style-type: none"> <li>a. <input checked="" type="checkbox"/> is attached hereto.</li> <li>b. <input type="checkbox"/> has been previously submitted under 35 U.S.C. 154(d)(4).</li> </ol> </li> <li>7. <input checked="" type="checkbox"/> Amendments to the claims of the International Application under PCT Article 19 (35 U.S.C. 371(c)(3))             <ol style="list-style-type: none"> <li>a. <input type="checkbox"/> are transmitted herewith (required only if not transmitted by the International Bureau).</li> <li>b. <input type="checkbox"/> have been communicated by the International Bureau.</li> <li>c. <input type="checkbox"/> have not been made; however, the time limit for making such amendments has NOT expired.</li> <li>d. <input checked="" type="checkbox"/> have not been made and will not be made.</li> </ol> </li> <li>8. <input type="checkbox"/> An English language translation of the amendments to the claims under PCT Article 19 (35 U.S.C. 371(c)(3)).</li> <li>9. <input checked="" type="checkbox"/> An oath or declaration of the inventor(s) (35 U.S.C. 371(c)(4)).</li> <li>10. <input type="checkbox"/> An English language translation of the annexes to the International Preliminary Examination Report under PCT Article 36 (35 U.S.C. 371(c)(5)).</li> </ol> <p><b>Items 11. to 16. below concern document(s) or information included:</b></p> <ol style="list-style-type: none"> <li>11. <input type="checkbox"/> An Information Disclosure Statement under 37 CFR 1.97 and 1.98.</li> <li>12. <input type="checkbox"/> An Assignment document for recording. A separate cover sheet in compliance with 37 CFR 3.28 and 3.31 is included.</li> <li>13. <input type="checkbox"/> A FIRST preliminary amendment.</li> <li>14. <input checked="" type="checkbox"/> An Application Data Sheet under 37 CFR 1.76.</li> <li>15. <input type="checkbox"/> A substitute specification.</li> <li>16. <input type="checkbox"/> A change of power of attorney and/or address letter.</li> <li>17. <input type="checkbox"/> A computer-readable sequence form of the sequence listing in accordance with PCT Rule 13ter.2 and 37 CFR 1.821-1.825.</li> <li>18. <input type="checkbox"/> A second copy of the published International Application under 35 U.S.C. 154(d)(4).</li> <li>19. <input type="checkbox"/> A second copy of the English language translation of the international application under 35 U.S.C. 154(d)(4)</li> <li>20. <input checked="" type="checkbox"/> Other items or information:             <ul style="list-style-type: none"> <li><input checked="" type="checkbox"/> Courtesy copy of the first page of the International Publication (WO 2004/019966 A1).</li> <li><input checked="" type="checkbox"/> Courtesy copy of the International Preliminary Examination Report. There were no annexes.</li> <li><input checked="" type="checkbox"/> Formal drawings, 1 sheet, Figures 1-4.</li> <li><input checked="" type="checkbox"/> Courtesy Copy of the International Search Report.</li> <li><input checked="" type="checkbox"/> The application is (or will be) assigned to: Chugai Seiyaku Kabushiki Kaisha whose address is 5-1, Ukima 5-chome, Kita-ku, Tokyo 115-8543, Japan.</li> </ul> </li> </ol> |   |   |

10/524019

DT05 Rec'd PCT/PTO 09 FEB 2005

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| U.S. APPLICATION NO. (If known, see 37 CFR 1.5) |  | International Application No.<br><b>PCT/JP2003/010754</b> |  | Attorney's Docket No.<br><b>TANIKAWA1</b> |  |
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21. The following fees are submitted:

|   |              |   |   |                 |  |          |     |  |            |  |        |              |              |                    |  |              |           |   |            |          |                    |         |   |            |          |   |  |  |            |          |   |          |  |
|---|--------------|---|---|-----------------|--|----------|-----|--|------------|--|--------|--------------|--------------|--------------------|--|--------------|-----------|---|------------|----------|--------------------|---------|---|------------|----------|---|--|--|------------|----------|---|----------|--|
| <p><b>[xx] a) BASIC NATIONAL FEE (37 CFR 1.492(a)).....\$300.00</b></p> <p><b>[xx] b) SEARCH FEE (37 CFR 1.492(b))</b></p> <p style="padding-left: 20px;"><input type="checkbox"/> US was International Searching Authority.....\$100.00</p> <p style="padding-left: 20px;"><b>[xx] Other ISR provided to USPTO by time search fee paid.....\$400.00</b></p> <p style="padding-left: 20px;"><input type="checkbox"/> All other situations.....\$500.00</p> <p><b>[xx] c) EXAMINATION FEE (37 CFR 1.492 (c))</b></p> <p style="padding-left: 20px;"><input type="checkbox"/> IPEA/US gave wholly favorable IPER.....\$100.00</p> <p style="padding-left: 20px;"><b>[xx] All other situations.....\$200.00</b></p> <p style="text-align: center;"><b>TOTAL OF ABOVE CALCULATIONS :</b></p> <p>Surcharge of \$130.00 for furnishing the oath or declaration later than <input type="checkbox"/> 20 <input type="checkbox"/> 30 months from the earliest claimed priority date (37 CFR 1.492(h)).</p> <table border="1" style="width:100%; border-collapse: collapse;"> <tr> <td style="width:15%;">TOTAL SHEETS</td> <td style="width:15%;">EXTRA SHEETS</td> <td style="width:30%;">Number of each additional 50 or fraction thereof (round up to a whole number)</td> <td style="width:15%;">RATE (1.492(g))</td> <td style="width:25%;"></td> </tr> <tr> <td>29 - 100</td> <td>/50</td> <td></td> <td>X \$250.00</td> <td></td> </tr> </table> <table border="1" style="width:100%; border-collapse: collapse;"> <tr> <td style="width:20%;">CLAIMS</td> <td style="width:20%;">Number Filed</td> <td style="width:20%;">Number Extra</td> <td style="width:20%;">Rate (1.492 (d-f))</td> <td style="width:20%;"></td> </tr> <tr> <td>Total Claims</td> <td>22 - 20 =</td> <td>2</td> <td>X \$ 50.00</td> <td>\$100.00</td> </tr> <tr> <td>Independent Claims</td> <td>5 - 3 =</td> <td>2</td> <td>X \$200.00</td> <td>\$400.00</td> </tr> <tr> <td>Multiple Dependent Claims (if applicable)</td> <td></td> <td></td> <td>+ \$360.00</td> <td>\$360.00</td> </tr> </table> <p style="text-align: right;"><b>TOTAL OF ABOVE CALCULATIONS = \$1,760.00</b></p> <p>Reduction of 1/2 for filing by small entity, if applicable. Applicant claims small entity status. See 37 CFR 1.27.</p> <p style="text-align: right;"><b>SUBTOTAL = \$1,760.00</b></p> <p>Processing fee of \$130.00 for furnishing the English translation later than <input type="checkbox"/> 20 <input type="checkbox"/> 30 months from the earliest claimed priority date (37 CFR 1.492(i)).</p> <p style="text-align: right;"><b>TOTAL NATIONAL FEE = \$1,760.00</b></p> <p>Fee for recording the enclosed assignment (37 CFR 1.21(h)). The assignment must be accompanied by an appropriate cover sheet (37 CFR 3.28, 3.31). \$40.00 per property +</p> <p style="text-align: right;"><b>TOTAL FEES ENCLOSED = \$1,760.00</b></p> | TOTAL SHEETS | EXTRA SHEETS  | Number of each additional 50 or fraction thereof (round up to a whole number) | RATE (1.492(g)) |  | 29 - 100 | /50 |  | X \$250.00 |  | CLAIMS | Number Filed | Number Extra | Rate (1.492 (d-f)) |  | Total Claims | 22 - 20 = | 2 | X \$ 50.00 | \$100.00 | Independent Claims | 5 - 3 = | 2 | X \$200.00 | \$400.00 | Multiple Dependent Claims (if applicable) |  |  | + \$360.00 | \$360.00 | <p style="text-align: center;"><b>CALCULATIONS PTO USE ONLY</b></p> <table border="1" style="width:100%; border-collapse: collapse;"> <tr> <td style="width:50%; height: 100px; vertical-align: top;">\$900.00</td> <td style="width:50%;"></td> </tr> </table> | \$900.00 |  |
| TOTAL SHEETS  | EXTRA SHEETS | Number of each additional 50 or fraction thereof (round up to a whole number) | RATE (1.492(g))   |                 |  |          |     |  |            |  |        |              |              |                    |  |              |           |   |            |          |                    |         |   |            |          |   |  |  |            |          |   |          |  |
| 29 - 100  | /50          |   | X \$250.00  |                 |  |          |     |  |            |  |        |              |              |                    |  |              |           |   |            |          |                    |         |   |            |          |   |  |  |            |          |   |          |  |
| CLAIMS  | Number Filed | Number Extra  | Rate (1.492 (d-f))  |                 |  |          |     |  |            |  |        |              |              |                    |  |              |           |   |            |          |                    |         |   |            |          |   |  |  |            |          |   |          |  |
| Total Claims  | 22 - 20 =    | 2   | X \$ 50.00  | \$100.00        |  |          |     |  |            |  |        |              |              |                    |  |              |           |   |            |          |                    |         |   |            |          |   |  |  |            |          |   |          |  |
| Independent Claims  | 5 - 3 =      | 2   | X \$200.00  | \$400.00        |  |          |     |  |            |  |        |              |              |                    |  |              |           |   |            |          |                    |         |   |            |          |   |  |  |            |          |   |          |  |
| Multiple Dependent Claims (if applicable)   |              |   | + \$360.00  | \$360.00        |  |          |     |  |            |  |        |              |              |                    |  |              |           |   |            |          |                    |         |   |            |          |   |  |  |            |          |   |          |  |
| \$900.00  |              |   |   |                 |  |          |     |  |            |  |        |              |              |                    |  |              |           |   |            |          |                    |         |   |            |          |   |  |  |            |          |   |          |  |

**Payment Method (check one only)**

a. ☐ A check in the amount of \$ \_\_\_\_\_ to cover the above fees is enclosed.

b. ☒ Credit Card Payment Form (PTO-2038), authorizing payment in the amount of \$1,760.00, is attached.

c. ☐ Please charge my Deposit Account No. 02-4035 in the amount of \$ \_\_\_\_\_ to cover the above fees.  
A duplicate copy of this sheet is enclosed.

**Handling of Fee Deficiencies (check one only)**

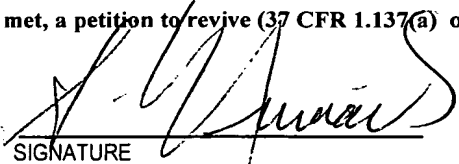
☒ The Commissioner is hereby authorized to charge any additional fees which may be required, or credit any overpayment to Deposit Account No. 02-4035. A duplicate copy of this sheet is enclosed.

☐ If a deficiency exists in the basic national fee set by 37 CFR 1.492(a), please charge it to Deposit Account 02-4035. At this time, no authorization is given to charge any other fees.

**NOTE: Where an appropriate time limit under 37 CFR 1.494 or 1.495 has not been met, a petition to revive (37 CFR 1.137(a) or (b)) must be filed and granted to restore the application to pending status.**

Direct all correspondence to the address associated with  
**CUSTOMER NUMBER 001444**, which is currently:

**BROWDY AND NEIMARK, P.L.L.C.**  
**624 NINTH STREET, N.W., SUITE 300**  
**WASHINGTON, D.C. 20001**  
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**Date of this submission: February 9, 2005**

  
 SIGNATURE  
 Sheridan Neimark  
 NAME  
 20,520  
 REGISTRATION NUMBER  
 SN:lmh